Line of Inquiry and source	Expectations
1.0 Sample Receiving, Log-in, and Transfer	
1.1 Written/controlled procedures are available at the work station. [ASME NQA-1]	Are there controlled copies of standard operating procedures (SOPs) available at the bench for activities being performed? Are they easily retrievable? Are they the most current version?
1.2 Condition of samples as received is checked and documented, including cold preservation, unusual conditions, chain-of-custody (COC) seals, and completeness of delivery according to the sample request sheet or COC form. [Laboratory quality assurance plan; Contract Laboratory Program (CLP), Exhibit F 1.3; SW-846, 4.3.1]	Upon sample receipt, are the following items checked: preservative, temperature, sample integrity, labels, seals, physical appearance, and COC match sample containers? Are signatures present? Who checks the pH and how is it checked? Is the pH documented? What happens if the pH is not within specifications?
1.3 Nonconformances during sample receiving are documented and, in instances where sample integrity may be compromised, the customer is immediately notified of problems. (ASME NQA-1; CLP, Exhibit F 1.3.7)	What mechanism is used to ensure immediate customer notification of nonconformance reports (NCRs)? What defines an NCR? How are NCRs handled?

Line of Inquiry and source	Expectations
1.4 COC is maintained while samples are in initial storage in the sample receiving area during all hours of the day, on weekends, holidays, etc. (CLP, Exhibit F 3.5 and 3.6)	How is sample security maintained? How is security maintained on weekends and holidays? Are refrigerators and sample storage areas secured? Who has access to these areas?
1.5 Sample refrigeration practices ensure and document that conditions remain within an acceptable range (4 ± 2°C). (SW-846 Chap. One, Sect. 4.3.1; CLP, Exhibit D, Sect. II; CLP, Exhibit A, Sect. 4.3.3.2)	Are there refrigerator temperature logs? With acceptance criteria? What happens when a malfunction occurs?
1.6 Monitoring for cross contamination is performed routinely for volatile organics sample storage refrigerators (i.e., refrigerator blanks). (CLP, Exhibit D, Sect. 12)	Are volatile organic samples segregated? How often are storage blanks installed? How often are storage blanks checked? What happens when a storage blank is contaminated?
1.7 Sample segregation practices are in place for waste and environmental (or high and low concentration) samples and for radioactive and nonradioactive samples. (SW-846, Chap. One, Sects. 4.1 and 4.3.1)	Are samples screened for radioactivity? How are radioactive samples handled? Is this information documented? If a sample screens “hot,” what process does the laboratory follow to properly label and segregate it from other samples? Are refrigerators available and marked for sample segregation?

Line of Inquiry and source	Expectations
1.8 Data from (1.7) are routinely assessed and evaluated by sample receiving room staff. Data are available for presentation to the auditor. (CLP, Exhibit D, Sect. 12)	Are the data available for review? Are all staff members aware of practices mentioned in Lines of Inquiry (LOI) 1.7?
1.9 Copies of completed COC forms are available for inspection. (CLP, Exhibit F 2)	Does COC have signature, date, and time received by the client and laboratory? Is there a signature, time, and date for each time COC is relinquished? Are copies of the completed COC kept in an orderly fashion and easily accessible?
1.10 COC is transferred to the analytical laboratory by a documented signoff. (CLP, Exhibit F 3.7)	Is COC documentation available? Is the documentation accurate? Does it include date, time, and signature of each relinquishment?
1.11 A sample receiving logbook is present that documents the chronological sequence and volume of samples processed through sample log-in. (CLP, Exhibit F 1.4)	Is a bound notebook used to document the receipt of samples and other pertinent information? Is QC performed after the initial log-in?
1.12 Logbooks are well maintained and legible. (CLP, Exhibit B, Sect. II)	Are proper record keeping methods used? Are initials and dates used when crossing-out is performed? Are unused pages properly “Z'd” out?
1.13 Controlled SOPs exist to cover sample control operations. (ASME NQA-1; CLP, Exhibit F 3.3)	Are SOPs current and available for all pertinent activities? Are employees understanding and working from the most current SOPs?

Line of Inquiry and source		Expectations
1.14	Employee training is routinely conducted on sample control operations. (ASME NQA-1)	Are designated sample custodians trained in sample control operations according to position requirements? Is this training documented and readily available in the employees training files?
1.15	Sample receiving/transfer logbooks are reviewed and initialed by a reviewer at regular frequencies. (CLP, Exhibit F 3.7; ASME NQA-1)	Is peer and/or supervisory review of all documents performed on a regular basis? Are the reviews documented by signature and date on the original document?
1.16	Sample receiving/transfer records are dispositioned to protected or dual storage. (ASME NQA-1; CLP, Exhibit F 3.7)	Are all records kept in dual and/or fireproof storage protected from loss by fire or other hazard? Is the laboratory storing records in fireproof cabinets or at another off-site facility? Are transfer records available?
2.0	**Sample Preparation and Cleanup**	
2.1	Are controlled SOPs at the workstation? (ASME NQA-1)	Are controlled copies of SOPs available at the workstation that document the laboratory's current practices? Are the SOPs verbatim or copies of U.S. Environmental Protection Agency (EPA) methodologies (i.e., SW-846)?
2.2	Is sample preparation performed on a clean tabletop? (SW-846, Chap. One, Sect. 4.1)	Is housekeeping adequate? (Cadmium contamination in dust particles; rusty hoods Fe, Zn, Cu contamination?) What is the general level of cleanliness of the laboratory preparation areas?

Line of Inquiry and source	Expectations
2.3 Sample preparation practices assure homogenization so that a representative aliquot is obtained for analysis? (*Analytical Support Agreement Terms and Conditions*, Article VII, I)	Is the analytical balance sensitive enough to meet method requirements? Does documentation exist with acceptance criteria? Are all analytical balances calibrated by an outside source once every 6 months? Are samples homogenized before weighing? How is this process performed?
2.4 Sample cleanup practices follow required EPA protocol. (Method-specific requirements)	Does organic sample cleanup follow the required protocol specified in the specific method used?
2.5 Laboratory glassware is scrupulously cleaned using a documented protocol. (SW-846, Chap. One, Sect. 4.3.3)	Is glassware used in the laboratory scrupulously cleaned and free from cracks, chips, or excessive scratches? QC samples should not be prepared in special glassware (i.e., beakers are used for blanks only). Is there an SOP for cleaning glassware? Does the SOP address requirements for the different sections of the laboratory (i.e., organics, inorganics, radiological)? Is there segregation of glassware for preparation areas?

Line of Inquiry and source	Expectations
2.6 Deionized and/or organic free water used in laboratory operations are routinely checked for purity and these checks are documented. (Standards Methods 1080 A and C)	What is the laboratory's water source? Who is responsible for monitoring water quality in the laboratory and documenting the results? Is the deionized water supply monitored for resistivity/conductivity? Are control limits set? What type of storage containers are used for deionized water for organic use?
2.7 Percent moisture determinations follow EPA procedures. (EPA Method 160.3)	Is percent moisture determined on all soil samples? Are all soil samples percent moisture-corrected?
2.8 Extraction/digestions procedures follow EPA protocol. (Method-specific requirements)	How is digestion performed (hotplate or microwave)? Is digestion performed on water samples (not required for some samples)? Are beakers labeled properly (i.e., method, volumes, and instrumentation)? Is aliquot reduction documented for the water matrix of radiochemistry? Is the digestion or leachate process documented and does it follow standard protocol?

Line of Inquiry and source	Expectations
2.9 Sample preparation logbooks are detailed, follow good logbook protocol, and include required information. (SW-846, Chap. One, Sects. 4.3.4, 4.3.10, and 4.6)	How is the preparation area notified of repreparations? Is detailed information about the preparation of samples documented in a bound notebook and include the following items? • sample number • pH checks and adjustments • time • EPA preparation method • sample weights • balance ID • initials of prep laboratory analyst • wet/dry weights and percent moisture • lot of solvents and reagents used • ID number of spike, internal standards, tracers and/or surrogates
3.0 Laboratory Logkeeping	
3.1 Logbooks are maintained in the laboratory for all key operations. (SW-846, Chap. One, Sect. 4.6)	Are the instrument maintenance and run logs maintained on a real-time basis? Does each laboratory area have logbooks for the following bulleted items? • standards preparation • instrument run logs • extractions/digestions/separations/distillations and other analytical operations • pH meter calibration • instrument maintenance logs

Line of Inquiry and source	Expectations
3.2 Logbooks are under a document control system. (SW-846, Chap. One, Sect. 4.6)	Are logbooks assigned a number? Are assigned log book numbers documented in a central logbook? Are logbooks archived in a timely manner after completion?
3.3 Logkeeping practices are defensible (i.e., pages are signed, corrections initialled and dated, blank spaces crossed out and dated/initialled, legible, neat professional quality). [*Good Laboratory Practices* (GLP), SW-846, Chap. One, Sect. 4.6]	Is the format of charts or data output clear enough to follow? Are charts and data output labeled correctly? Do instrument print-outs document the instrument, operator, date, time, and analysis?
3.4 Completed logbooks are protected from loss. (SW-846, Chap. One, Sect. 4.6)	Are completed logbooks kept in dual storage and in order for easy access? Is the storage location fireproof?
4.0 Standards and Reference Materials	
4.1 Standards are traceable to EPA or National Institute of Standards and Technology (NIST) certified standards, including the following: • initial calibration standards • continuing calibration standards • spiking standards • chemical tracers • surrogates • deuterated analogues • counting standards • others (list) (ASME NQA-1; SW-846, Chap. One "Definitions"; Standard Methods 1040B.2 and 7020)	What certified standard is used? All working standards must be verified before use, and this documentation must be maintained in an organized manner. All solvents and reagents (Na_2SO_4, florissil, and deionized water) must be checked on a lot-by-lot basis before put into use in the laboratory. (Organic) All acids and reagents (H_2O_2, HCl, HNO_3, H_2SO_4, and $SnCl_2$) must be checked on a lot-by-lot basis before use in the laboratory. (Metals)

Line of Inquiry and source	Expectations
4.2 Certificates are kept on file for standards and reference materials. (ASME NQA-1)	Are all certificates kept in a central location? Are reference standards traceable to the certificates? Are there certificates available for each standard reviewed?
4.3 Preparation of standards is documented in a logbook. (SW-846, Chap. One, Sect. 3.3.2)	Is proper documentation available for preparation of working standards, spike solutions, and laboratory control sample (LCS) solutions? Are all of the following items listed in the logbook? • genealogy of the standard all the way to its source, • description of volumetric or mass dilution methods for preparation, • ID numbers of all balances and pipettes used during preparation, and • name of person preparing the standard Are all items being documented properly and according to procedure? Is the documentation complete?
4.4 Working standards are assigned a unique ID number traceable to the standards logbook. (GLP, Chap. 9, "Test, Control and Reference Standard Characterization," p. 120; GLP Chap. 9, p. 124)	Are spike solutions labeled properly? Are they traceable to NIST, EPA, or source? All standards should be labeled with a unique ID, preparation date, expiration date, name of standard, and solvent or diluent used. Are the ID numbers traceable to a logbook?

Line of Inquiry and source		Expectations
4.5	Shelf lives are tracked for spikes, standards, and reference materials.	Are expired standards stored in a separate area from standards in use until disposal? What mechanism is in place to tell the laboratory it has an expired standard? How are expired standards traced?
4.6	Shelf lives are labeled on the container.	Are reagents labeled properly (date received, date expired, date prepared, and concentration)?
4.7	Standards are protected in a controlled area cabinet or refrigerator. (ASME NQA-1)	Are standards stored separate from reagents? Are incompatible standards stored separately? Is the storage location secure?
4.8	Standards are stored separately from samples. (CLP, Exhibit E 5.2.1)	Are standards and other reagents or samples stored separately?
4.9	Organic standards are properly refrigerated and stored as required by the specific EPA method. (CLP, Exhibit E 5.2.1)	Are standards and reagents properly stored according to method protocol?
4.10	Stock solutions or standards that are kept for long periods are frequently checked for stability against quality control samples. (CLP, Exhibit E 5.3.2)	Is there a set schedule for verifying that “aged” standards are still stable?
5.0	**Instrument Calibration and Tuning**	
5.1	Controlled procedures are present at the work station that list requirements for instrument calibration and tuning. (SW-846, Chap. One, Sect. 4.3.5)	The laboratory should have SOPs in place that detail exactly how they perform calibration and tuning of each instrument. These SOPs have requirements for acceptable calibration and tuning.

Line of Inquiry and source	Expectations
5.2 Initial calibration is performed in the sequence and at the frequency required by the EPA method. (SW-846, Chap. One, Sect. 4.3.5)	Is the calibration of instruments adequate? Is all pertinent information documentated?
5.3 Initial calibration data are well documented for each instrument/detector, including ID number of standard used, time, analyst name, detector/ instrument number, and calibration date. (SW-846, Chap. One, Sect. 4.6)	Is all pertinent information documented on instrument calibration records?
5.4 Instrument tuning (mass spectrometry instruments only) is performed according to EPA-required protocol.	Is the EPA protocol followed for gas chromatograph/mass spectrometry tuning?
5.5 Acceptance criteria are defined and documented for all initial calibration and tuning operations. (SW-846, Chap. One, Sect. 4.6)	Is the calibration curve acceptable? [The correlation coefficient (R) should be $\geq$ 0.995.] Is the calibration linear or nonlinear? (Criterion for metals only.) The correlation coefficient should be $\geq$ 0.999 for organics. Does the laboratory have set acceptance criteria for initial calibration?
5.6 Initial calibration and tuning results are checked against acceptance criteria and nonconformances are corrected according to EPA or standard method requirements (Method-specific requirements).	Are calibration and tuning results checked against method-specific control limits or control limits set by the laboratory? Are the laboratory control limits as strict as the method protocols?
5.7 Initial calibrations are verified against a check standard that is prepared from an independent source (SW-846, Chap. Three, Sect. 3.1.2; SW-846 8000A, Sect. 8.0).	Is calibration verified by analyzing an independent standard?
5.8 Continuing calibration checks are made, as required by method, to confirm sustained acceptability of initial calibration (Method-specific requirements).	Are continuing calibration checks analyzed at the required concentrations and frequencies specified in the method?
5.9 Acceptance criteria are defined and documented for continuing calibration results (Method-specific requirements).	Does the laboratory have set control limits?

Line of Inquiry and source		Expectations
5.10	Full calibration is performed if continuing calibration checks are unacceptable. (Method-specific requirements; SW-846 Chap. Three; SW-846 8000A)	Are recalibrations performed when continuing calibration fails to meet acceptable criteria?
6.0	**Quality Control Samples and Control Charts**	
6.1	Quality control (QC) sample analysis and frequency are adequate. Frequency of one per preparation batch for each method blank, duplicate, matrix spike and QC check sample. QC checked samples are prepared from an independent source. (SW-846, Chap. One)	Are duplicates, matrix spikes, matrix spike duplicates, method preparation blanks, and LCSs being analyzed? Are QC samples analyzed at the proper frequency and are laboratory control limits meeting the specific method-required acceptance criteria? Does the laboratory perform blank spikes (LCS)? Are duplicates being run? What are the acceptance criteria for QC samples? Does the laboratory do spike recovery correction?
6.2	The spike is carried through the entire analytical process. (SW-846, Chap. One)	Are automatic pipettes routinely checked for accuracy? Are the results of the checks documented? What are the control limits?
6.3	Standards, spikes, and QC samples are traceable to documented certificates of accuracy and/or purity. (SW-846, Chap. One, Sect. 4.4.3)	Are QC samples and QC standards traceable to the manufacturer's certificate of analysis?
6.4	Procedures exist for review and acceptance of QC sample results, including established limits for which data must be reviewed against. (SW-846, Chap. One, Sect. 4.4.2)	Are the matrix spike levels acceptable? Are acceptable criteria available?

Line of Inquiry and source		Expectations
6.5	Statistical control charts are maintained for accuracy and precision. (SW-846, Chap. One, Sect. 4.4.2)	Are Shewhart control charts plotted for each matrix and each analysis performed by the laboratory?
6.6	Acceptability of QC samples to performance criteria is checked as soon as possible after data generation, and these checks are well documented. (Laboratory quality assurance plan and method-specific requirements)	Are QC samples checked against control limits during or immediately after analysis? Is this verification documented?
6.7	Corrective actions are established in procedures for QC sample results that exceed the control limits. (SW-846, Chap. One, Sect. 4.4.3)	If a QC sample does not fall within acceptable limits, what is done to correct this? Are NCRs filed?
7.0	**Analytical Method Documentation**	
7.1	Standard procedures exist on specifically how the laboratory implements each standard EPA method. (SW-846, Chap. One, Sect. 4.3)	Are controlled copies of SOPs in place and available at the bench? Do the SOPs document current laboratory practices? Make sure the SOPs are <u>not</u> copies or repeats of EPA methods (SW-846, CLP, etc.).
7.2	Deviations from EPA methods are documented in laboratory SOPs. (SW-846, Chap. One, Sect. 4.4.4)	Are deviations from methods documented and communicated to the Sample Management Office? Can the required detection limits be achieved using these deviations? Were method detection limits performed with deviation?
7.3	Logsheets or standardized logbooks exist to document the operational steps of each SOP. (GLP, Chap. 15; SW-846, Chap. One, Sect. 4.6)	Does a bound notebook exist to document all pertinent information? Is the same information documented for each sample batch?

Line of Inquiry and source	Expectations
7.4 Method detection limits are established for all common matrices and these are current. (SW-846, Chap. One, Sect. 4.4)	Are MDLs performed annually? Are the MDLs current and supporting of detection limits? What is the frequency of verification? How many runs are preferred? Are MDLs available for all matrices?
7.5 Instrument detection limits are established and current. (40 CFR 136, Appendix B; Standard Method 1030E)	How are detection limits determined? What is the frequency of verification? Is detection limits establishment documented? Are established detection limits documented properly? Are IDLs performed for each instrument used?

Line of Inquiry and source		Expectations
8.0	**Data Review and Reporting Within the Analytical Laboratory**	
8.1	Procedures exist for data review and reporting including: • supervisor reviews in the laboratory, • independent technical review of data, and • data package completeness review. (SW-846, Chap. One, Sect. 2.7.2)	Is there a reporting procedure in place? What percent of the data are validated? Are data reviews completed by supervisory/peer/quality assurance (QA)? Are significant figures checked? Have appropriate units been documented? What is the length and type of data storage?
8.2	Rigorous data review occurs within the laboratory and covers the following items: • All QA/QC criteria are checked. • Data are checked on a 100% frequency to ensure reliability. • Data completeness is checked (i.e., did we do and report all that was requested by the client). • Ancillary data needed for data defensibility (refrigerator logs, standards prep logs, balance and oven logs, etc.) are independently reviewed and checks are documented. • Reviews are well documented. (SW-846, Chap. One, Sect. 2.6)	How and to what extent are data reviewed? Are data acceptance criteria acceptable? Are sample runs documented in a bound notebook? What methods are used for analysis?
8.3	The analytical laboratory can readily prepare detailed data packages of the EPA Level III and IV format without extensive manual transcription. (*Analytical Support Agreement Terms and Conditions*, "General Deliverables for All Analyses")	Can the laboratory prepare a "full" data package without extensive manual data entry?

Line of Inquiry and source		Expectations
8.4	If manual transcriptions or data entry occurs, these steps are identified and special controls are in place to check for human error. (SW-846, Chap. One, Sect. 4.4.6)	Does someone other than the data entry person check all manual entries?
8.5	Types of problems requiring NCRs have been identified. NCRs are issued when these types of problems occur. (ASME NQA-1)	Are problems that require an NCR documented? When a problem requiring an NCR occurs, who receives the report?
8.6	Corrective actions are formally tracked to prevent recurrence. (ASME NQA-1)	Are NCRs and corrective actions tracked and is there a procedure in place for addressing problems to prevent recurrence?
8.7	Nonconformances are closely monitored by quality assurance staff and are evaluated to the appropriate level to prevent recurrence. (ASME NQA-1)	Does QA staff take an active role in tracking NCRs and their corrective actions to prevent recurrence of problems?
9.0	**Data Package Preparation and Reporting to Customer**	
9.1	Data packages are assembled in manner that assures completeness. (CLP, Exhibit B 2.0)	Does the laboratory have a checklist to follow to ensure package completeness?
9.2	The final product is checked against established acceptance criteria before release to the client. (CLP, Exhibit B 2.0)	Does someone check the package before it is issued to the client?
9.3	The laboratory certifies under signature that the data package is accurate and complete and that the electronic version and hard copies match. (CLP, Exhibit A, Sect. 4.2.3.1)	Is there a designated qualified person to sign the final package before release to the client?